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UTILITY PATENT APPLICATION TRANSMITTAL (only for new nonprovisional applications under 37 CFR 1.53(b))	*Attorney Docket No.*	JJM-381
	First Named Inventor or Application Identifier	Paul William Watt, Reginald Stilwell and Alan LeBlanc
	Express Mail Label No.	EM550067794US

APPLICATION ELEMENTS

See MPEP Chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. ☒ Fee Transmittal Form *(attached hereto in duplicate)*
2. ☒ Specification [Total Pages 18]
   (Preferred arrangement set forth below)
   - Descriptive Title of the Invention
   - Cross References to Related Applications
   - Statement Regarding Fed sponsored R&D
   - Reference to Microfiche Appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
3. ☒ Drawing(s)*(35 USC 113)* [Total Sheets4]
4. Oath or Declaration
   - a. ☐ Newly executed (original or copy)
   - b. ☒ Unexecuted original
   - c. ☐ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional check boxes 5 and 16)*
     - i. ☐ Deletion of Inventor(s)
       Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation by Reference *(useable if Box 4c is checked)*
   The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4c, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
6. ☐ Microfiche Computer Program (Appendix)
7. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
   - a. ☐ Computer Readable Copy
   - b. ☐ Paper Copy (identical to computer copy)
   - c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. ☐ Assignment Papers (cover sheet & document(s))
9. ☐ 37 CFR 3.73(b) Statement *(when there is an assignee)* ☐ Power of Attorney
10. ☐ English Translation Document *(if applicable)*
11. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
12. ☐ Preliminary Amendment
13. ☒ Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
14. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
15. ☐ Other:

16. If a CONTINUING APPLICATION, *check appropriate box and supply the requisite information:*
☐ Continuation ☐ Divisional ☐ Continuation-in-Part (CIP) of prior application No:

17. For this divisional application, please cancel original Claims of the prior application before calculating the filing fee.

18. CORRESPONDENCE ADDRESS

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19. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

NAME	Andrew C. Farmer	Reg. No. 35,868
SIGNATURE	[signature]	
DATE	October 1, 1998	

FEE TRANSMITTAL	*Complete if Known*	
	Application Number	
	Filing Date	October 1, 1998
	First Named Inventor	Paul William Watt et al.
	Group Art Unit	
	Examiner Name	
	Attorney Docket Number	JJM-381

FEE CALCULATION

CLAIMS AS FILED

(1)	(2)	(3)	(4)	(5)
FOR:	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE $790.00
TOTAL CLAIMS	25 - 20 =	5	x 22.00	$ 110.00
INDEPENDENT CLAIMS	3 - 3 =	0	x 82.00	$ 0.00
MULTIPLE DEPENDENT CLAIMS	☐	N/A	$270.00	
			TOTAL FEES	$ 900.00

METHOD OF PAYMENT

☒ Please charge Deposit Account No. 10-0750/JJM381/ACF in the amount of $900.00. Three copies of this sheet are enclosed.

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SUBMITTED BY:			*Complete (if applicable)*
Typed or Printed Name	Andrew C. Farmer		Reg. No. 35,868
Signature	[signature]	Date: October 1, 1998	**Deposit Account No. 10-0750**

BIOPOLYMER SPONGE TUBES, SURGICAL STAPLERS AND METHODS OF USE THEREOF

Field of the Invention

The present invention relates to biopolymer sponge tubes and the use thereof in surgery.

Background of the Invention

Surgical staple guns are widely used in the haemostasis and subsequent sealing of tissue following surgical procedures. For example, in the sealing of tissue following lung volume reductions for patients with emphysema.

Typically, the linear surgical staplers have two separate barrels of differing dimensions, namely a staple cartridge and an anvil, which close together during the stapling. The Burdorff, U.S. Patent No. 5,697,543 issued December 16, 1997, the Bittner et al., U.S. Patent No. 5,673,842 issued October 7, 1997, and the Schulze et al., U.S. Patent No. 5,065,929 issued November 19, 1991, each of which are incorporated herein by reference, provide examples of surgical staplers.

Often surgical staplers are indicated for use with a buttressing material, such as bovine pericardium, which surgeons use to reinforce staple lines and prevent leaks. According to current surgical procedure, the pericardium is wrapped around the barrels of the stapler prior to use. In use, the two barrels of the staple gun are placed on either

side of the tissue that requires sealing. The stapling action brings together the two barrels with the pericardium, which is stapled into position at the appropriate site. The pericardium then acts as a seal to prevent exudate/air leakage.

The use of bovine pericardium in the above stapling procedure suffers from the drawbacks of possible antigenicity of the bovine pericardium, and lack of control over the precise shape, configuration and thickness of the bovine pericardium.

It is known to use pledgets of material to achieve hemostasis along a staple line as shown in the Trumbell et al., U.S. Patent No. 5,263,629, issued November 23, 1998 and incorporated herein be reference. Trumbell et al. provide rectangular pledgets of a fabric-like material, preferably having hemostatic properties, between the anvil and the staple cartridge in a surgical stapler. Staples are fired through both the pledget and the tissue to adhere the pledget to the tissue along the staple line. Placement and retention of the pledgets in the stapler can be quite tricky.

It is known to provide collagen tubes by the extrusion of a collagen gel into a coagulating bath. Such tubes have been used in micro-surgery, and for vascular prostheses. Implanted collagen films and/or collagen sponges have been suggested as slow-release matrices for therapeutic agents. The properties and applications of collagen biomaterials have been reviewed by A. Huc in Journal of American

Leather Chemists Association, Vol. 80, pages 195-212 (1985).

US-A-3157524 describes forming porous collagen tubes by freezing an aqueous collagen slurry in a tubular mold, followed by solvent drying in an anhydrous isopropanol bath.

Alternatively, the slurry may be frozen onto the outside of a tube through which a suitable refrigerant is passed, followed by solvent drying. The sponges are said to control bleeding in surgery through the application of pressure and coagulating material such as thrombin. No specific applications are disclosed.

It has now been found that biopolymer sponge tubes are highly suitable for replacing bovine pericardium and rectangular pledgets in the surgical stapling procedure described above.

Summary of the Invention

Accordingly, the present invention provides a biopolymer sponge tube closed at one end.

The biopolymer sponge tube is closed at one end to enable it to be fitted over a barrel of a staple gun without sliding too far along the barrel.

The present invention also provides a surgical stapler comprising a staple cartridge and an anvil, and having a

biopolymer sponge tube (which need not be closed at one end) fitted over the staple cartridge and/or over the anvil. Preferably, biopolymer sponge tubes are fitted over each of the staple cartridge and the anvil. Preferably, the biopolymer sponge tube or tubes are closed at one end.

The present invention further provides the use of a biopolymer sponge tube for the preparation of a surgical stapler as above for use in surgery.

The biopolymer used to make the sponge tubes may be any biocompatible and bioabsorbable polymer. Preferably, the biopolymer is selected from the group consisting of structural proteins, cellulose derivatives (including oxidised regenerated cellulose), starch derivatives, chitin, chitosan, glycosaminoglycans, and mixtures thereof. Preferred structural proteins include gelatin, all collagen types, keratin, laminin, fibrin or fibronectin. The phrase "all collagen types" encompasses type I and type II collagen, atelocollagen and other modified collagens. Suitable cellulose derivatives include carboxymethyl cellulose and hydroxyethyl cellulose, in addition to oxidised regenerated cellulose. Suitable alginates include sodium alginate, calcium alginate and mixtures thereof. Suitable glycosaminoglycans include hyaluronic acid, chondroitin sulphate, heparin and heparan sulphate.

The biopolymer sponge tube may be reinforced by a biopolymer matrix, such as a Vicryl (registered trade mark) polylactide/polyglycolide mesh. However, preferably, the biopolymer sponge is not reinforced.

Preferably, the biopolymer sponge tube consists essentially of one of more collagen types. The collagen may be chemically cross-linked to modify its physical properties and rate of resorption in vivo. Collagen is the preferred biopolymer because of its easy availability, low cost, low antigenicity, and well-understood properties, which enable the collagen sponge to be prepared with controlled physical and biological behaviour.

The biopolymer sponge tube is preferably sterile. Preferably, the biopolymer sponge tube comprises less than 10% by weight of water to enable it to be stored indefinitely without decomposition. The biopolymer sponge tube preferably further comprises a therapeutic compound selected from the group consisting of antiseptics, such as chlorhexidine, antibiotics such as streptomycin, analgesics such as ibuprofen, steroids, cell growth factors and wound healing factors. Preferably, the therapeutic compound is present in amount of 0.01% to 2% by weight, based on the weight of the biopolymer sponge tube.

Preferably, the biopolymer sponge tube is fully bioabsorbable in the mammalian body. This makes it especially suitable for use in conjunction with surgical stapling procedures, especially in endoscopic surgery. The rate of bioabsorption of the biopolymer can be controlled by cross-linking the biopolymer.

The biopolymer sponge tubes according to the present invention preferably have substantially uniform internal and external cross-sections. Preferably, the wall thickness of the tubes is also substantially constant.

Preferably, the internal and external cross-sections are both substantially circular or rectangular. Preferably, the average internal diameter of the biopolymer sponge tubes is from 3mm to 30mm, or preferably 5mm to 20mm, and the wall of the biopolymer sponge tube has a substantially uniform uncompressed wall thickness in the range of 1 to 4mm. Preferably, the ratio of the length to the average external diameter of the biopolymer sponge tubes is in the range of 2:1 to 10:1, preferably 3:1 to 5:1. These preferred shapes and dimensions are especially suitable for fitting the biopolymer sponge tube over one or other barrel of a surgical stapler.

The biopolymer sponge tubes for use in the present invention are preferably prepared by a process comprising: providing an aqueous dispersion of the biopolymer; introducing the dispersion into a tube-shaped mould, following by freezing the dispersion to provide a shaped frozen dispersion; and freeze-drying or solvent-drying the shaped frozen dispersion to form the biopolymer sponge tube.

Preferably, the aqueous dispersion comprises 0.05-2.5% w/v of the biopolymer. The aqueous dispersion may be buffered to an optimum pH, and may also comprise therapeutic active agents for incorporation into the final biopolymer sponge tube. The aqueous dispersion may also contain emulsified lipid droplets for incorporation into the biopolymer sponge tube, as described and claimed in our patent application EP-A-0567234, and its U.S. equivalent, U.S. Patent No. 5,660,857 issued August 26, 1997 which is incorporated herein by reference, and which provide several

benefits including enhancing liquid impermeability of the resulting collagen product.

A chemical cross-linking agent, such as glutaraldehyde or hexamethylene diisocyanate (HMDI) may be incorporated in the aqueous dispersion, or may be used to treat the biopolymer sponge tube following the drying step.

The tube-shaped mould is preferably in the shape of a tube closed at one end. If it is intended that the final biopolymer sponge tube should be reinforced with a bioabsorable mesh, such as a Vicryl™ (registered trade mark) polylactide-polyglycolide mesh, then the mesh is inserted into the mould with the aqueous dispersion prior to freezing.

Preferably, the frozen aqueous dispersion is removed from the mould prior to drying. This can be achieved by warming the mould slightly and inverting the mould to allow the frozen aqueous dispersion to drop from the mould. Preferably, the central part of the mould defining the inside wall of the tubular frozen aqueous dispersion can be warmed and removed from the mould automatically. More preferably, the end (i.e. base wall) of the mould is moveable in piston fashion along the length of the mould to expel the frozen aqueous dispersion from the mould.

Preferably, an array of tube-shaped moulds is provided for simultaneous moulding and freezing of a plurality of frozen aqueous dispersions. More preferably, the steps of

pouring the aqueous dispersion into the mould, freezing, and expelling the frozen aqueous dispersion from the mould are alternated.

The shaped frozen dispersion is freeze-dried or solvent-dried to form the biopolymer sponge tube. Freeze-drying is typically carried out at -10°C to +20°C overnight. Solvent drying is preferably carried out in a succession of baths of anhydrous isopropyl alcohol as described in US-A-3157524, the entire content of which is expressly incorporated herein by reference.

The dried biopolymer sponge tube is preferably packaged in aseptic packaging, and then dry sterilised, preferably by gamma-irradiation.

Specific embodiments of the present invention will now be described further, by way of example, with reference to the accompanying drawings, in which:

Brief Description of the Drawings

Figure 1 shows schematic cross-sectional views of stages in a process for preparing an open-ended biopolymer sponge tube;

Figure 2 shows schematic cross-sectional views of stages in a process for preparing a biopolymer sponge tube closed at one end according to the present invention;

Figure 3 shows schematic top-plan view (a) and cross-sectional views (b)-(d) of stages in a process similar to

that of Figure 2, but adapted for automated production of multiple biopolymer sponge tubes closed at one end;

Figure 4 shows a schematic side view of a surgical staple gun; and

Figure 5 shows the staple gun of Figure 4 fitted with biopolymer sponge tubes according to the invention.

Detailed Description

Procedure 1: Preparation of open-ended Fibrous Collagen Sponge Tube

Lyophilised collagen is prepared as described in US Patents nos. 4614794 or 4320201, the entire contents of which are expressly incorporated herein by reference. The lyophilised collagen is re-suspended in cold 0.05M acetic acid at a concentration of 1% w/v. The pH is adjusted to 3.0 with acetic acid. The resulting slurry is poured into a cylindrical mould 1 as shown in cross-section in Figure 1(a). The mould with the slurry 2 therein is frozen at -40°C as shown in Figure 1(b). The frozen slurry is removed from the mould by slightly warming the mould, and inverting the mould to allow the tube to slip from the mould as shown in Figure 1(c). The frozen tube 3 is transferred immediately to a freeze-dryer and freeze-dried to form a collagen sponge tube 4.

The resulting freeze-dried collagen tube is soft and conformable, bioabsorbable, and also exhibits useful

haemostatic properties when applied with a surgical stapler.

Procedure 2: Preparation of Soluble Collagen Sponge Tube

The procedure described above in Procedure 1 is repeated, replacing the fibrous lyophilised collagen by pepsin-solubilised collagen at a concentration of 10mg/ml. The resulting sponge tube is water soluble.

Procedure 3: Preparation of cross-linked Collagen Sponge Tube

The procedure of Procedure 1 is repeated, but with cross-linking of the collagen in the aqueous slurry. The lyophilised collagen as in Procedure 1 is resuspended in 0.05M acetic acid at a concentration of 1%w/v. The pH is adjusted to 3.0. Hexamethylene dusocyanate (HMDI) is added at 2%w/w collagen and homogenised in a Waring Blendor (3 x 30s). The resulting slurry is formed into collagen sponge tubes exactly as described in Procedure 1.

Procedure 4: Preparation of Gelatin Sponge Tube

The fibrous collagen slurry prepared as in Procedure 1 is gelatinised by heating to 60°C for one hour. The slurry is then processed into a biopolymer sponge tube as in Example 1.

Procedure 5: Preparation of Collagen/ORC Sponge Tubes.

Lyophilised collagen, prepared as described in U.S. Patent No. 4614794 or 4320201, is resuspended in cold 0.OSM acetic acid at a concentration of 10mg/ml. Milled ORC powder (milled SURGICEL® oxidised regenerated cellulose cloth) is added to the suspension in a ration of 1:3 ORC: collagen and homogenised using a Waring Blendor on low speed for 3 x 10s. The slurry is degassed in a vacuum oven for 10 min and then poured into the appropriate mould. The mould with the slurry is then processed as described in Procedure 1.

Example 1: Preparation of Biopolymer Sponge Tubes with Closed End

Biopolymer sponge tubes closed at one end are prepared as shown in schematic cross-section in Figure 2. A biopolymer slurry as described in Procedures 1-6 is poured into a mould in the shape of a closed-end tube and formed from an outer shell and a central mandrel 6. The slurry and mould are frozen at -40°C. The central mandrel 6 of the mould is warmed slightly and removed from the inside of the cast open-ended tube 7. The outer shell 5 of the mould is then inverted and warmed slightly to release the frozen slurry in the shape of a tube closed at one end 7. The cast, frozen tube is then immediately freeze-dried to give a biopolymer sponge tube closed at one end 8.

Example 2: Multiple Moulding of Biopolymer Sponge Tubes

Figure 3 shows an apparatus 10 for the multiple, automated production of biopolymer sponge tubes closed at

one end. The apparatus comprises an array of wells 11 defining the outer parts of the moulds, and a complementary array of mould mandrels 12 for insertion into the wells. The floor 13 of each mould well is mounted on a piston 14, and is slideably moveable inside the well 11 to push the frozen, cast tubes 15 out of the wells following the casting and freezing steps. The frozen tubes 15 are collected and freeze-dried.

Example 3: Use of Biopolymer Sponge Tubes on Surgical Stapler

Figure 3 shows a schematic view of a surgical staple gun 20 for use in lung volume reduction surgery. The staple gun is provided with a stapler cartridge barrel 21 and an anvil barrel 22. In use, biopolymer sponges tube 23,24 having a closed end are slipped over the end of each of the cartridge barrel 21 and the anvil barrel 22 as shown in Figure 5.

The two barrels 21,22 of the staple gun 20, with the biopolymer sponge tubes 23,24 in place, are then placed on either side of the tissue that requires sealing. The stapling action brings together with two barrels whilst the tubes, which flatten during the stapling procedure, are stapled into position at the appropriate site. The flattened biopolymer tubes then act as a seal to prevent exudate/air leakage, and where appropriate to encourage haemostasis.

Use of surgical staples in lung resection is known to those of skill in the art. Such procedure is enhanced when

biopolymer sponge tubes according to the present invention are used with the stapler in effecting the lung resection.

The above embodiments have been described by way of example only. Many other embodiments falling within the scope of the accompanying claims will be apparent to the skilled reader.

WHAT IS CLAIMED IS:

1. A biopolymer sponge tube which is closed at one end.

2. A biopolymer sponge tube according to claim 1 wherein the biopolymer is selected from the group consisting of structural proteins, cellulose derivatives including oxidised regenerated cellulose, starch derivatives, chitin, chitosan, alginates, glycosaminoglycans and mixtures thereof.

3. A biopolymer sponge tube according to claim 2, wherein the biopolymer is selected from the group consisting of gelatin, all collagen types, keratin, laminin, fibrin or fibronectin.

4. A biopolymer sponge tube according to claim 3, wherein the biopolymer consists essentially of collagen.

5. A biopolymer sponge tube according to claim 1 and further comprising a therapeutic compound selected from the group consisting of antiseptics, antibiotics, analgesics, steroids, cell growth factors and wound healing factors.

6. A biopolymer sponge tube according to claim 1 which is fully bioabsorbable in a mammalian body.

7. A biopolymer sponge tube according claim 1 having an average internal diameter of from 3mm to 30mm.

8. A biopolymer sponge tube according claim 7 having a substantially uniform uncompressed wall thickness of from 1 to 4mm.

9. A biopolymer sponge tube according to claim 1, wherein the ratio of length to average external diameter is in the range of 2:1 to 10:1.

10. A biopolymer sponge tube according to claim 1, wherein the biopolymer comprises collagen having droplets of lipids dispersed therein.

11. A surgical stapler comprising a staple cartridge and an anvil, and having a biopolymer sponge tube fitted over the staple cartridge and/or over the anvil.

12. A surgical stapler according to claim 11 wherein the biopolymer is selected from the group consisting of structural proteins, cellulose derivatives including oxidised regenerated cellulose, starch derivatives, chitin, chitosan, alginates, glycosaminoglycans and mixtures thereof.

13. A surgical stapler according to claim 12, wherein the biopolymer is selected from the group consisting of gelatin, all collagen types, keratin, laminin, fibrin or fibronectin.

14. A surgical stapler according to claim 13, wherein the biopolymer consists essentially of collagen.

15. A surgical stapler according to claim 11 wherein the biopolymer sponge tube further comprises a therapeutic compound selected from the group consisting of antiseptics, antibiotics, analgesics, steroids, cell growth factors and wound healing factors.

16. A surgical stapler according to claim 11 wherein the biopolymer sponge tube is fully bioabsorbable in a mammalian body.

17. A surgical stapler according to claim 11, wherein the biopolymer comprises collagen having droplets of lipids dispersed therein.

18. A method for stapling mammalian tissue comprising the steps of:

placing the tissue between a staple cartridge and an anvil in a surgical stapler;

fitting a biopolymer sponge tube over the staple cartridge and/or over the anvil; and

firing at least one staple from the staple cartridge through the biopolymer sponge tube and through the tissue to thereby attach the biopolymer sponge tube to the tissue.

19. A method according to claim 18 wherein the biopolymer is selected from the group consisting of structural proteins, cellulose derivatives including oxidised regenerated cellulose, starch derivatives, chitin, chitosan, alginates, glycosaminoglycans and mixtures thereof.

20. A method according to claim 19, wherein the biopolymer is selected from the group consisting of gelatin, all collagen types, keratin, laminin, fibrin or fibronectin.

21. A method according to claim 20, wherein the biopolymer consists essentially of collagen.

22. A method according to claim 18 wherein the biopolymer sponge tube further comprises a therapeutic compound selected from the group consisting of antiseptics, antibiotics, analgesics, steroids, cell growth factors and wound healing factors.

23. A method according to claim 18 wherein the biopolymer sponge tube is fully bioabsorbable in a mammalian body.

24. A method according to claim 18 wherein the tissue is lung tissue being joined in a lung resection.

25. A method according to claim 18 wherein the biopolymer sponge tube comprises collagen containing a lipid material dispersed therein.

ABSTRACT

The invention provides biopolymer sponge tubes closed at one end for use in surgery. The preferred biopolymer iscollagen. The biopolymer sponge tubes are prepared by forming an aqueous dispersion of the biopolymer, introducing the dispersion into tube-shaped moulds, freezing the dispersion in the moulds to form a shaped, aqueous dispersion, followed by freeze-drying the frozen aqueous dispersion. The tubes are fitted over endoscopic surgical staplers to provide improved sealing of stapled tissues, especially for air-tight sealing in lung resections.

FIG. 1(a)

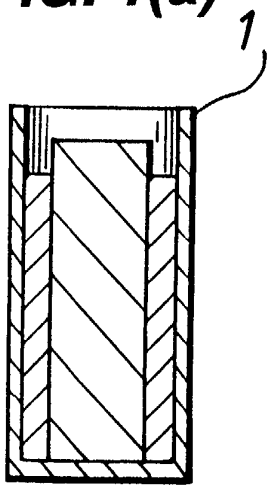


FIG. 1(b)

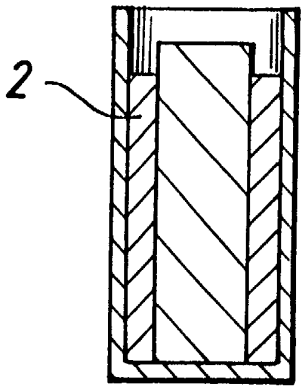


FIG. 1(c)

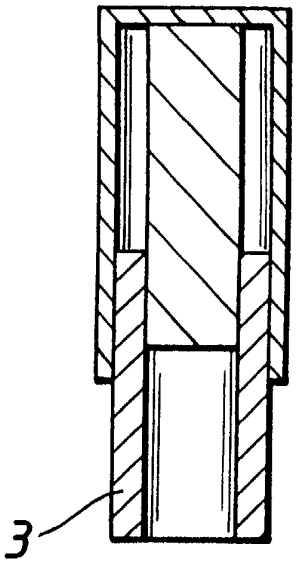


FIG. 1(d)

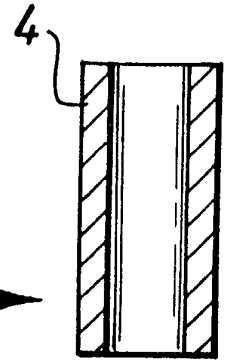


FIG. 2(a)

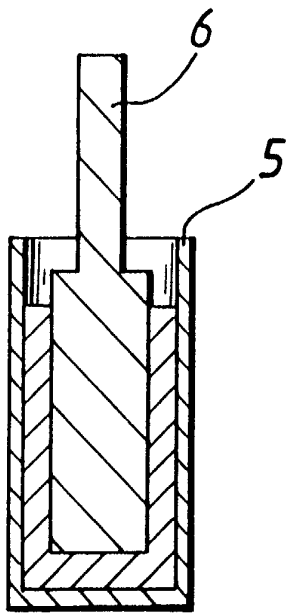


FIG. 2(b)

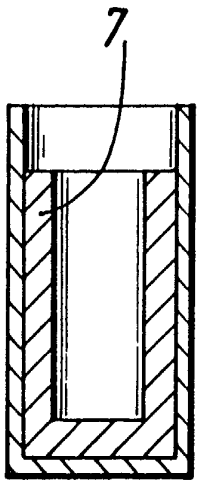


FIG. 2(c)

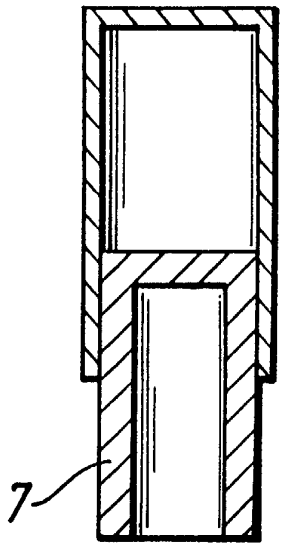


FIG. 2(d)

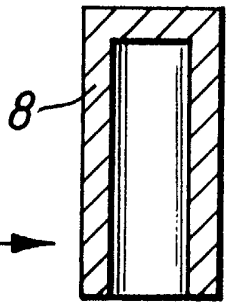


FIG. 3(a)

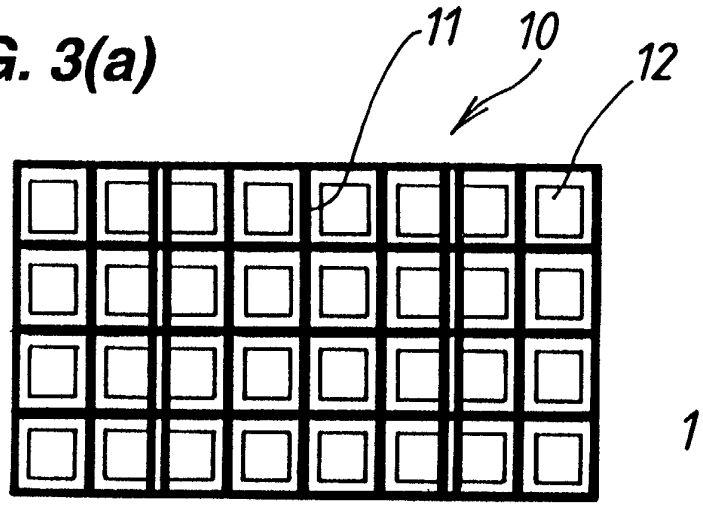


FIG. 3(b)

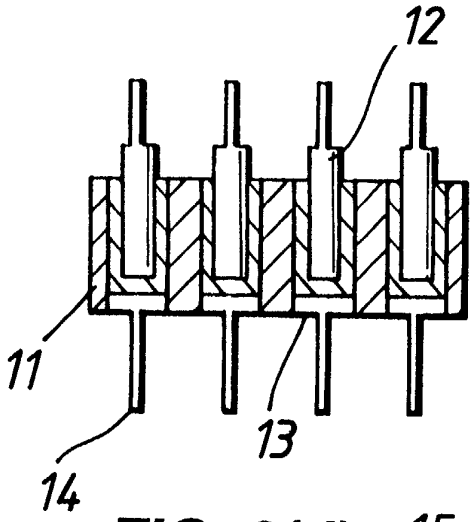


FIG. 3(c)

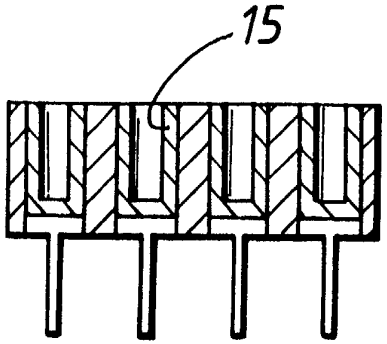


FIG. 3(d)

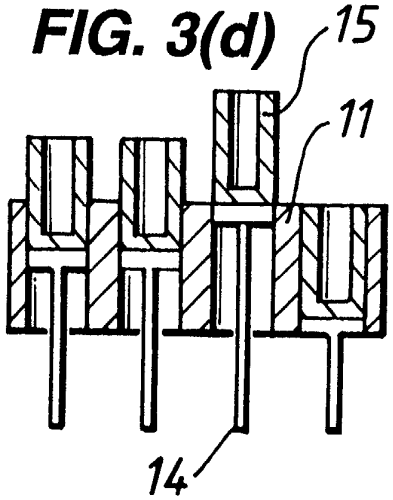


FIG. 4

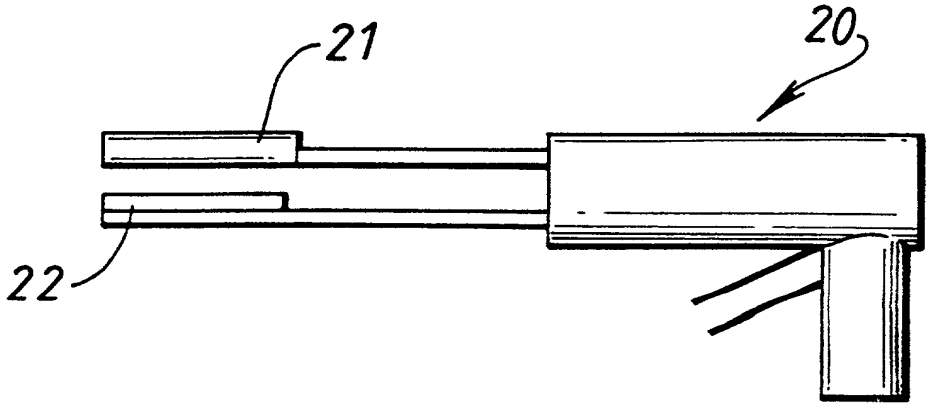
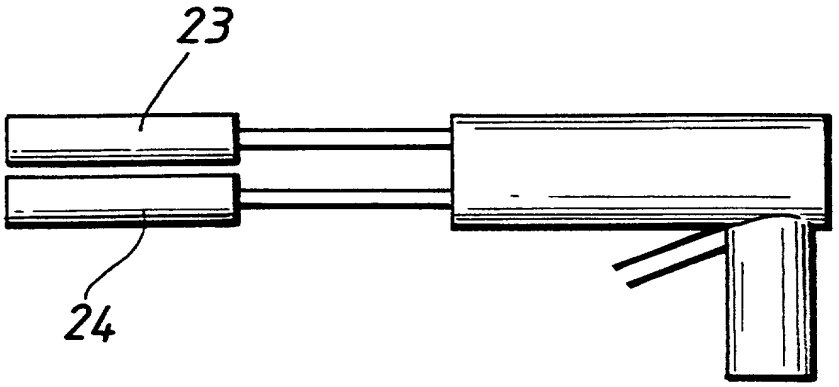


FIG. 5



DOCKET NO. JJM-381

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled BIOPOLYMER SPONGE TUBES, SURGICAL STAPLERS AND METHODS OF USE THEREOF, the specification of which

(check one) ☒ is attached hereto.

☐ was filed on _____ as

Application Serial No. _____

and was amended on _____.
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 (a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s):

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C. 119
United Kingdom	9721079	October 3, 1997	☒ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

(Application Number) (Filing Date)

(Application Number) (Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No. Filing Date Status

Application Serial No. Filing Date Status

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith as well as to file equivalent patent applications in countries foreign to the United States including the filing of international patent applications in accordance with the Patent Cooperation Treaty: Audley A. Ciamporcero, Jr. (Reg. #26,051), Steven P. Berman (Reg. #24,772), Andrea L. Colby (Reg. #30,194), Michael Stark (Reg. #32,495), and Andrew C. Farmer (Reg. #35,868) One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

Address all telephone calls to Andrew C. Farmer at telephone no. (732) 524-2825.

Address all correspondence to Audley A. Ciamporcero, Jr., One Johnson & Johnson Plaza, New Brunswick, NJ 08933-7003.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Inventor's Signature: ______________________

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Date: ______________

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